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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,474	04/07/2004	Preeti Lal	039386-1568	7560
22428 7590 05/07/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER LANDSMAN, ROBERT S	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 05/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,474

Applicant(s)

LAL ET AL.

Examiner

Robert Landsman, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment filed 4/10/07 has been entered into the record.
- B. Claims 56-64 are pending and are the subject of this Office Action.

2. Specification

- A. The objection to the title has been withdrawn in view of Applicants' amendments.
- B. The objection to the specification has been withdrawn in view of Applicants' submission of the Tables.
- C. The specification remains objected to since the status of 09/720,533 has not been updated.

3. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- A. Claims 56-64 remain rejected under 35 USC 101 for the reasons already of record on pages 2-3 of the Office Action mailed 2/1/07. Applicants argue that SEQ ID NO:43 of the present invention shares 99% identity with RELM-beta (FIZZ) protein. However, no disclosure of this homology could be found in the specification. The utility of the invention needs to be disclosed in the application as filed. MPEP 2107 II(B) states:

Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible

In the instant situation, neither the claims nor the specification provide any supporting written description that the protein is a RELM-beta (FIZZ) protein. The fact that the protein may be used as, or involved in, the laundry list of molecules described on pages 1-2 and 5-6 of the specification does not provide a specific substantial use for the claimed protein.

4. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 56-64 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 2/1/07 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. Claims 56, 59, 60, 61 and 63 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 2/1/07. First, though Applicants thank the Examiner for stating that SEQ ID NO:43 and 177 are enabled, it is noted that this, respectfully, is completely accurate. In the rejection at the top of page 4 of the Office Action it states "even if claims 56-64 possessed utility." Therefore, to clarify, SEQ ID NO:43 and 177 would be enabled. However, they do not possess utility which, in a matter of speaking, is the most serious of the enablement rejection.

Regardless, Applicants argue that the specification provides a detailed description of the changes that can be made to the claimed sequences, including information taught by Patel regarding cysteine residues. These arguments have been considered, but are not deemed persuasive. The claims do not recite any specific functional limitations. The Examiner is of the viewpoint that Applicants' arguments regarding the allowed protein alterations or requirement for cysteine residues, does not provide sufficient guidance as to what alterations can be made. However, even *arguendo*, the points argued by Applicants were persuasive, the fact remains that no limitation has been provided *in the claims*.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 56, 59, 60, 61 and 63 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4 of the Office Action mailed 2/1/07. Applicants' arguments are identical to that for enablement. Therefore, the Examiner's arguments are identical.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. The rejection of claims 56, 59, 60 and 63 under 35 USC 102(e) is withdrawn in view of Applicants' arguments that Gurney et al. does not qualify as prior art based on priority dates. It is noted, however, that only SEQ ID NO:43 of the present invention deserves priority to June 26, 1998. It appears that SEQ ID NO:177 receives priority only to the date of the instant application, April 7, 2004. However, since the claims only recite the full-length of SEQ ID NO:177, no prior art could be found.

7. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Landsman, Ph.D.
Primary Examiner
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